Individual Safety Report

3622738-6-00-01

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 133633

E FDA MEDICAL PRODUCTS REPORTING PROGRAM

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C&R

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted]902 In confidence	6/15/61	☒ female ☐ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ____ (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 6/24/00

4. Date of this report (mo/day/yr): 6/28/00

5. Describe event or problem

39 YOF with hx EtOH abuse, alcoholic hepatitis, pancreatitis. On 6/17, pt reported inc epigastric pain radiating to back and RUQ which worsened with inspiration and food. Pt saw MD and CT negative. Pt RX with Darvocet for pain. At home, pt ingested Darvocet X 2 and ES APAP X 3 on 6/20, ES APAP X 3 on 6/21, and ES X 3 on 6/22. Pain worsened and N/V dvlpd. Pt at OSH ED on 6/23 with elev LFTs and tx here 6/24. PT assumed to hace chronic hepatitis with an acute flare possibly related to APAP ingestion. Acetylcys RX started. Pt improving slowly.

6. Relevant tests/laboratory data, including dates

	6/25	6/26	6/27
Tbili	1.6	1.1	0.7
GGT	412	348	282
ALT	1999	929	628
AST	1948	257	106
ALK	186	151	131
INR	1.3	1.3	1.2

6/25 Amylase 31 Lipase 221

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Allergies: Flagyl - rash, Indocin - HA, T3's → esophageal spasm

PMH: EtOH abuse, alcoholic hepatitis, pancreatitis, DT's

CTG 133633

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler if known)
#1 (1) Acetaminophen (2) Darvocet
#2

2. Dose, frequency & route used
#1 500mg tid x3 days
#2 2 tabs x1

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
#1 6/20-6/22
#2 6/20

4. Diagnosis for use (indication)
#1 Pain
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
Flexeril, KCl, MgSO4

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

5. Expiration date (mo/day/yr)

6.
model # RECEIVED
catalog # DEC 0 6 2000
serial #
lot # MEDWATCH CTU
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone
[redacted]

2. Health professional? occupation
☐ yes ☐ no Pharmacist

3. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

FDA Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178